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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,585	10/16/2001	Avi J. Ashkenazi	P2630P1C15	5223

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,585	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 58-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 58-63 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/9/02, 2/.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Part III: Detailed Office Action

Claims 58-63 are pending and under consideration.

The claims are drawn to anti-PRO526 polypeptide antibodies, SEQ ID NO: 400.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities:

Applicants are advised that the ATCC has moved from Rockville, MD to Manassas, VA, effective March 23, 1998. The correct address is now:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Appropriate correction is required.

IDS:

The information disclosure statement, filed 5/6/2002, has been considered. The BLAST results demonstrate that applicants are aware of nucleic acids with identity/homology to the one claimed herein. However, as the BLAST results do not give sufficient identifying information, the Examiner cannot determine if said sequences constitute prior art.

Priority Determination:

The utility for the claimed nucleic acids is based upon Example 126, at page 351, in which it is shown that the polypeptide encoded by the protein is active in a chondrocyte redifferentiation assay. The earliest disclosure of this result that can be confirmed by the Examiner is in US Application 09/918585, filed 7/30/01. It is suspected that priority may exist in PCT/US99/28313 or PCT/US00/04341. Applicants are requested to provide a copy of that portion of each application which contains the chondrocyte redifferentiation assay in response to this office action to allow a proper priority determination. Accordingly, priority is set at 7/30/01, with possible priority to 11/30/99 or 2/18/00, pending review of the PCT applications.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to the date recited above which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to that date.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 states that the claimed antibody "binds" the protein of SEQ ID NO: 12, whereas dependent claim 63 states that the antibody "specifically binds". The term "specifically" in claim 63 is a relative term that renders the claim indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, the use of the term in the dependent claim raises the issue that the antibodies of the other claims may *not* be specific to the protein, in which case the metes and bounds of the claims are in question.

Claim 61 is further indefinite as an antibody cannot be a fragment of itself.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

Priority is set at 7/30/01, but may be granted to 11/30/99 or 2/18/00. Accordingly, the rejections below are being set forth with each possible priority date in mind.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 58-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruben et al., U.S. Patent Number 6,475,753.

Ruben et al. disclose and claim a protein, SEQ ID NO: 161, that is 99.7% identical to residues 1-361 of SEQ ID NO: 400 of the instant application, having a sole mismatch at residue 135. Antibodies to the protein are also disclosed, see abstract, for example.

At paragraph 797 of the Brief Summary of the Invention, Ruben et al. state:

> Further polypeptides of the invention relate to antibodies and T-cell antigen receptors (TCR) which immunospecifically bind a polypeptide, polypeptide fragment, or variant of SEQ ID NO:Y, and/or an epitope, of the present invention (as determined by immunoassays well known in the art for assaying specific antibody-antigen binding). Antibodies of the invention include, but are not limited to, polyclonal, monoclonal, multispecific, human, humanized or chimeric antibodies, single chain

antibodies, Fab fragments, F(ab') fragments, fragments produced by a Fab expression library, anti-idiotypic (anti-Id) antibodies (including, e.g., anti-Id antibodies to antibodies of the invention), and epitope-binding fragments of any of the above.

At paragraph 784 of the Brief Summary of the Invention, Ruben et al. disclose labelled antibodies. Thus, the antibodies disclosed by Ruben et al. anticipate the claimed invention.

Claims 58-59 and 61-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Lalgudi et al., U.S. Patent Number 6,476,212. Lalgudi et al. disclose a number of polynucleotides and polypeptides derived from corn ear. SEQ ID NO: 6510 of Lalgudi et al. is 88.7% identical over its entire length (309 nucleotides) to nucleotides 1854-2161 of SEQ ID NO: 399 of the instant application. Vectors, host cells, expression of protein, and production of antibodies are discussed at columns 32-35, for example, and include polyclonal, monoclonal, chimeric, single chain, fragments (col. 34, lines 7-12), labelled antibodies (col. 35 lines 34-36). Thus, the claimed invention is anticipated by Lalgudi et al.

Claims 58-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Strittmatter, WO 01/51520. This disclosure merits priority to the filing date of US Provisional Application 60/207366, filed 5/26/2000.

Strittmatter discloses a protein designated NOGO receptor, having SEQ ID NO: 2, encoded by SEQ ID NO: 1. Strittmatter's SEQ ID NO: 2 is 100% identical to SEQ ID NO: 400. Strittmatter's SEQ ID NO: 1 is 100% identical to the entirety of the coding region of SEQ ID NO: 399. Claims are drawn to nucleic acids, vectors, host cells, protein, chimeric proteins, antibodies (monoclonal, polyclonal, humanized) etc. Antibody fragments are disclosed at page 7. Humanized antibodies are disclosed at pages 33-34. Labelled antibodies are disclosed at page 35. Thus, the invention is anticipated by Strittmatter et al.

Claims 58-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Fraser et al., WO 01/09162. This disclosure merits priority to the filing date of US Application 09/365164, filed 7/30/1999.

Fraser discloses a nucleic acid, having SEQ ID NO: 73, which they designate human TANGO 393 (page 73). Fraser's SEQ ID NO: 73 is 99.9% identical to SEQ ID NO: 399, nucleotides 475-2236, which comprises the entire coding sequence, and in fact is 100% identical to the entirety of the coding region of SEQ ID NO: 399. Claims are drawn to nucleic acids, vectors, host cells, protein, chimeric proteins including Ig fusion proteins (see page 113), antibodies (including monoclonal) etc. Polyclonal and monoclonal antibodies and antibody fragments are also disclosed at page 117, chimeric and humanized antibodies at page 119, and labelled antibodies at page 120. Thus, the invention is anticipated by Fraser et al.

Conclusion:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number will be 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623. ***Effective 1/21/2004, Dr. Kunz' telephone number will be 571-272-0887.***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228. ***Effective 1/21/2004, Dr. Spector's fax number will be 571-273-0893.***

Lorraine Spector, Ph.D.
Primary Examiner

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1/15/2004